

REMARKS***Summary of Amendments Made to the Specification***

The specification has been amended to correct a typographical error for occurrence of the unit of measurement "mm". This was intended to be readable upon μm . It is believed that the Greek symbol was erroneously converted into the letter "m". Support for the amended unit of measurement can be found throughout the specification (see e.g. page 8, lines 25-30).

Summary of Amendments Made to the Claims

Note: Claim 3 as presented in the amendment filed with the RCE had a typo which has been corrected (i.e. referring to "0.04" instead of 0.05 as previously presented)

Claims 2, 3, 10, 11 and 25 have been amended to define that the hydrophobic active ingredient are part of a hydrophobic inclusion.

Claim 5 has been amended as it was previously dependent upon itself. It is presumed that the examiner's 112, second para rejection was directed toward claim 28 instead of 24; the lack of antecedent basis has been corrected. It is believed that no new matter has been added.

Claims 2-41 are pending (the finality of the restriction requirement has been petitioned; as of the date of this response, the outcome of the petition is unknown. As such, the response is directed toward the claims rejected in the examiner's first office action on the merits.

It is also noted that claim 11 has been amended to depend upon claim 2 and as such the product and process claims are "linked". Should the subject matter of claims 2-10 and 28-41 be held allowable, it is requested that claims 11-27 be rejoined with the allowed subject matter. MPEP 821.04 (Rejoinder) states that "Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called under 35 U.S.C. 121 to elect claims to either the product or the process. See MPEP § 806.05(f) and § 806.05(h). The claims directed to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if an applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

Claims 2-10 and 28-41 are under examination and claims 11-27 are currently withdrawn from consideration. It is believed that no new matter has been added.

35 U.S.C. 103(a) rejections

Claims 2-10 and 28-37 were rejected as being obvious over Carr et al. (U.S. Patent 5,183,690) in view of Tsuei et al. (U.S. Patent 5,589,194).

While the Carr references has some similarities with regard to secondary components of the composition, the Carr reference has at least **two major differences** when compared with the applicants' claimed invention which are not remedied when combined with Tsuei.

The **first difference** is that Carr does not teach or suggest the inclusion size (i.e. 0.01 - 2 microns) as claimed by the applicants. When considering Carr's invention as a whole, it can be seen that the starch granules used to encapsulate various agents are at least a couple of order of magnitude greater in size than the inclusions claimed by the applicants. The broadest range of the granules used in the examples of Carr is from 10-40 mesh (which is equivalent to about 400 - 1500 microns) which is consistent with their recited means for preparing their compositions and the different purpose of the starch granules in the composition of Carr.

The examiner relies on Tsuei to account for the size differences of the inclusion but acknowledges that Tsuei does not explicitly mention the specific size of the inclusions. The rationale for combining Tsuei with Carr is that one of ordinary skill would have discovered the optimal size through routine experimentation (presumably relying on *In re Aller* from MPEP 2144.05 II. A.).

However, the very next section of the MPEP, i.e. 2144.05 II. B., makes clear that this standard can only be established if "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)." Neither Carr nor Tsuei recognized this particular parameter with the applicants claimed range as being a result-effective variable; Tsuei only teaches "proper balance of pressure, temperature and viscosity" not the formation of an oil-in-water emulsion and/or hydrophobic inclusions to control size. Moreover, even if use of an oil-in-water emulsion was recognized as a results-effective variable for size, one of ordinary skill in the art would not view going from a range of 400 - 1500 microns to 0.01 - 2 microns as being "routine experimentation".

The **second difference** is predicated on the presumed motivation(s) for using the Carr reference by the examiner, i.e. Carr teaches the use of starches as encapsulating materials and the applicants' claims encompass the use of starches as part of a composition which contains inclusions. However, these are widely divergent inventions.

The starch, as used in the applicants invention, is part of the hydrophilic thermoplastic matrix not the hydrophobic inclusions (see Example 2, Sample C - starch extrudate particles are 500 - 600 μm which is consistent with the arguments made explaining the "first difference") and as such do not function to encapsulate the active ingredient. As such, if the starches used by Carr are intended to be equivalent to the applicants' hydrophilic thermoplastic matrix, then there are no hydrophobic inclusions taught by Carr.

Alternatively, the applicants invention forms inclusions by taking advantages of the properties of the active ingredients, i.e. hydrophobic active as part of a hydrophobic inclusion. It appears that Carr's encapsulation is a physical encapsulation (i.e. starch granules encapsulate the ingredient and are not part of a matrix as in the applicants invention) and as such it is unclear if this actually meets the requirement of hydrophobic inclusion/hydrophobic active as in the applicants' claims as amended. If the examiner takes official notice or argues for inherency, the applicants hereby formally request that evidence be presented in support of these positions (see MPEP 2144.03 and 2112, respectively)

In addition, the reason the Carr and Tsuei references appear so different from the applicants claimed invention (or are not more suggestive of the elements of the applicants' invention) is that the applicants' claimed invention is prepared by a method which is not taught or suggested by the Carr and Tsuei reference, i.e. the applicants' first form an oil-in-water emulsion with the hydrophobic active ingredient wherein the oil phase then becomes the hydrophobic inclusion comprising the hydrophobic active ingredient after combining the oil-in-water emulsion with the hydrophilic thermoplastic matrix. This enables the practitioner to obtain inclusions and at sizes which are much smaller than those possible by more conventional techniques as taught by Carr and Tsuei.

Even if it were permissible to pick and choose elements from references as needed and/or to optimize conditions or ranges as needed from selected prior art, one of ordinary skill in the art lacking the knowledge to first form the oil-in-water emulsion would not arrive at the applicants' claimed invention without undue experimentation.

Therefore, the applicants believed that the claims as amended are unobvious in light of the Carr and Tsuei references and as such the examiner would be justified in rescinding this rejection.

Claims 38-41 were rejected as being obvious over Carr et al. and Tsuei et al., *supra*, further in view of Bilbrey (U.S. 5,290,547).

As the Bilbrey reference is only relied upon to combine specific emulsifiers to the teachings of Carr and Tsuei, the response to the Carr and Tsuei references made above are to be considered repeated here. With regard to the addition of Bilbrey, it is well known that "... 'Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.' see *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998).

Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (13 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 7 July 2003

By: Vilma I. Fernandez
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